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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/975,139

10/10/2001

Volker Schellenberger

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7590

02/09/2005

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EXAMINER

MAHATAN, CHANNING

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/975,139

**Applicant(s)**

SCHELLENBERGER ET AL.

**Examiner**

Channing S Mahatan

**Art Unit**

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6, 11, 14-23, 25-29 and 31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11, 14-23, 25-29 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### *REQUEST FOR CONTINUED EXAMINATION*

A request for continued examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. § 1.114, and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. § 1.114. Applicants' submission filed on 22 November 2004 has been entered.

### *APPLICANTS' ARGUMENTS*

Applicants' arguments, filed 22 November 2004, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### *CLAIMS UNDER EXAMINATION*

Claims herein under examination are claims 1-6, 11, 14-23, 25-29, and 31. Claims 7-9, 12, 13, 24, and 30 have been canceled.

### **Claims Rejected Under 35 U.S.C. § 112 2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 11, 14-22, and 29 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

*VAGUE AND INDEFINITE*

Claim 11 recites the following steps: “d) applying said constraint vector to said probability matrix to produce a substitution scheme; and e) creating a library of DNA sequences, wherein said library is constructed in a bacterial host” which is considered vague and indefinite. It is unclear if the produced substitution scheme of step d) is intended to be applied in the creation of the library of DNA sequences of step e) or if other additional steps/limitations, which are absent from the instant claims, are intended in the library construction. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 14-22 recites the limitation “unique DNA sequences” which is considered vague and indefinite. It is unclear what Applicants’ consider “unique DNA sequences” to encompass in the absence of a characterization/criteria defining said “unique DNA sequences” when compared to other “DNA sequences” (i.e. not unique). Clarification of the metes and bounds, via clearer claim language, is requested.

Claim 29 recites the limitation “wherein the DNA sequence is generated from DNA shuffling” which is confusing. It is unclear if Applicants intend the above limitation to be directed to the DNA sequence of step a) or step e). Clarification of the metes and bounds, via clearer claim language, is requested.

### **Claims Rejected Under 35 U.S.C. § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 6, 11, 23, 25-27, and 31 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hatfield et al. (U.S. Patent Number 5,082,767).

Hatfield et al. discloses a method for determining the pattern of non-random codon pair usage of an organism (Abstract; and Figure 1). Nucleotide sequence data for an organism is obtained (instant claims 1 & 11 step a); Abstract). The number of codons represented in at least a portion of the sequence and the frequency of usage of at least some codons in the portion is determined (instant claims 1 & 11 step b) and claim 23 “probability matrix”; Abstract; Column 8, lines 16-18). The frequency of the expected number of occurrences of at least some codon pairs are determined (instant claims 1 & 11 step c) and claim 25 “constraint vector”; Column 2, lines 41-45; Column 8, lines 18-28). The expected number is then compared with the actual number of occurrences to determine relative codon pairing preferences (instant claim 1 step e), instant claim 11 step d), and instant claim 31 step a) “applying the “constraint vector” to the “probability matrix” to derive a recommended substitution scheme”; Column 8, lines 28-34). The authors indicate the application of the codon pair preferences (i.e. substitution scheme) in altering or constructing genes for the purpose of expression in other organism (i.e. *E.coli*) (instant claims 1, 11, and 31 “library is produced in a bacterial host”; Column 1, lines 14-19, 23-49, and 46-48). Hatfield et al. state the presence of a particular codon at one position has been

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shown to strongly influence the frequency of the occurrence of certain nucleotides in neighboring codons (instant claims 5 & 6 “structural characteristics” i.e. residue chemistry & proximity to the site of functionality; Column 2, lines 40-45). The disclosed method is a computer program (instant claims 26 and 27; Column 13, lines 7-15). Thus, Hatfield et al. anticipates the instantly claimed invention.

### **Claims Rejected Under 35 U.S.C. § 103**

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1-6, 11, 23-28, and 31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hatfield et al. (U.S. Patent Number 5,082,767) taken in view of Blattner et al. (The Complete Genome Sequence of Escherichia coli K-12. Science. 05 September 1997, Volume 277, pages 1453-1462).

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Hatfield et al. is herein applied from above (refer to 35 U.S.C. 102(b) Rejection). Hatfield specifically indicated the utilization of the *E.coli* genome in the disclosed invention (Column 16, lines 23-31), however, Hatfield et al. fails to specifically recite the utilization of particular proteins of *E.coli* to be “esterase, dehydrogenase, and hydrolase” or “a protease, cellulose, lipase, hemicellulase, laccase, and amylase”.

Blattner et al. discloses the complete genome sequence of *E.coli* and indicates proteins of therein. For example, the authors indicate dehydrogenase (instant claims 2 & 3; page 1454, left column, line 57), hydrolase (instant claims 2 & 3; page 1457, right column, line 5), and receptor (instant claim 4; page 1459, right column, line 61) proteins.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the invention to practice Hatfield et al. (U.S. Patent Number 5,082,767) in view of Blattner et al. to utilize the specific proteins (as indicated above) in the method of determining the pattern of non-random codon pair usage of an organism since Hatfield et al. indicates the utilization of the *E.coli* genome.

#### EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either 571-273-8300.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify Applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables Applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Examiner Initials: *CSM*Date: *February 4, 2005*  
*△**Ardin H. Marschel 2/5/05*  
**ARDIN H. MARSCHEL**  
**PRIMARY EXAMINER**